K123638

510(k) Summary

FEB 2 1 2013

Applicant's Name and Address

Submitter: Cendres+Métaux SA
Rue de Boujean 122
2501 Biel/Bienne, Switzerland
Phone: +41 58 360 20 00
Fax: +41 58 360 20 10

Contact Person: Tanja Bongni
Regulatory Affairs Manager

Date of Submission: October 30, 2012

Name of the Device

Trade Name: Pekkton® ivory
Common Name: Crown and bridge, temporary, resin
Classification Name: Temporary crown and bridge resin
Regulation Number: 21 CFR 872.3770

Legally Marketed Device to which Equivalence is Claimed (Predicate Device)

Predicate Devices:		
Straumann RC Temporary Abutment	Telio® CAD	KMD-Mark1 Tissue Marker
K093027	K093708	K093473

Figure 1: Predicate Devices

For details please refer to chapter "Comparison / Compatibility; Substantially Equivalence".

Description of the Device

Device Description: Pekkton® ivory is a semi-crystalline thermoplastic supplied in blanks. Pressing the blank gives a framework, from which the dental technician manufactures the final veneered dental crown and / or temporary dental bridge.

Intended Use of the Device: Pekkton® ivory is intended to be used for long-term, temporary dental crowns and bridges frameworks.

Summary Technological Characteristics:

The proposed Pekkton® ivory is substantially equivalent to the performance of the predicate devices. The difference between our device and the predicates is incidental and not significant.
Any differences do not affect the safety and effectiveness of the device when used as labeled.

The material is a semi-crystalline thermoplast.

Comparison /Compatibility Substantially Equivalence:

The proposed Pekkton® ivory is substantially equivalent to the performance of the corresponding predicate devices. The difference between our device and the predicates is incidental and not significant.
Any differences do not affect the safety and effectiveness of the device when used as labeled.

Figure 2 summarizes the substantial equivalence comparison to the predicate devices:

		Predicate Devices			
	Pekkton® ivory	Straumann RC Temporary Abutment	Telio® CAD	KMD-Mark1 Tissue Marker	Remark
USA: 510(k) no	(This submission)	K093027	K093708	K093473	
Device Description, Design	Dental crown and bridge, temporary resin. Non-sterile.	Dental prosthetic temporary restoration. Non-sterile.	Dental crown and bridge, temporary resin. Non-sterile.	Implantable Radiographic Marker.	Similar device description as Telio® CAD.
Regulation, Product Code	872.3770, EBG	872.3630, NHA (for the Abutments)	872.3770, EBG	878.4300, NEU	Same regulation as Telio® CAD
Indications for use	Long term crowns / temporary 3-unit bridges	The RC Temporary Abutments are intended for use in Straumann RC Bone Level Dental Implant for temporary restorations of single crowns and bridges for up to six months.	Temporary veneered crowns / bridges (up to 4 units)	Implantable clip. Radiographically mark soft tissue during a surgical procedure or for future surgical procedures	Same indications for use as Telio® CAD
Material	Base Material: PEKK +Pigments	PEEK (white) with titanium inlay	Base Material: Polymethylmethacrylate, +Pigments	Base Material: PEKK +Pigments	Same base material as KMD-Mark1
Chemical and physical properties, Performance	According to material data sheet	According to raw material data sheet	According to material data sheet	Not relevant	Most similar physical and chemical properties as Telio® CAD and / or Straumann RC Temporary Abutment
Processing route,	Melt processing	Raw material: Melt	Non relevant	Not applicable	Similar manufacturing

		Predicate Devices			
	Pekkton® ivory	Straumann RC Temporary Abutment	Telio® CAD	KMD-Mark1 Tissue Marker	Remark
mechanism	(heat and pressure) of thermoplastic	processing (heat and pressure) of thermoplastic			principle as Straumann RC Temporary Abutment

Figure 2: Device Comparison Table

We conclude that for all significant parameters (please refer to Figure 2, column "Remark") Pekkton® ivory is substantially equivalent to its above mentioned predicate devices.

Summary of Testing to Demonstrate Safety and Effectiveness / Conclusion:
For the risk assessment of biological risks, the procedures and provisions of EN ISO 10993-1:2009 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process", were applied. Based upon the criteria set out in this standard, the product is biologically classified as an "external communicating device" with "permanent" (> 30 days) contact to "tissue, bone or dentine".

Therefore, in accordance with the aforementioned standards and in accordance with EN ISO 7405:2008 Dentistry – Preclinical Evaluation of Biocompatibility of Medical Devices Used in Dentistry – Test Methods for Dental Materials and in accordance with "510(k) Memorandum - #G95-1 Attachment B – Table 2 Supplementary Evaluation Tests for Consideration", the following risks were particularly considered:

- Cytotoxicity — EN ISO 10993-5:2009
- Irritation — EN ISO 10993-10:2010
- Delayed Type Hypersensitivity — EN ISO 10993-10:2010
- Acute Systemic Toxicity — EN ISO 10993-11:2009
- Subchronic and chronic systemic toxicity — EN ISO 10993-11:2009
- Implantation — EN ISO 10993-6:2009
- Genotoxicity — EN ISO 10993-3:2009
- Carcinogenicity — EN ISO 10993-3:2009

- Chemical characterization — EN ISO 10993-18:2009
- USP Plastic Class VI — USP 34 (88)

The following investigations regarding biocompatibility were conducted:

USP Plastic Class VI Testing
The biological reactivity of the Pekkton® ivory was investigated in compliance with international GLP regulations, using the USP Plastic Class VI test regimen pursuant to USP 34 <88>.
In summary, the testing provided the following results: The systemic injection tests exhibited no adverse clinical signs. Considering the reported data, it is concluded that the test material Pekkton® ivory meets the requirements of the USP Plastic Class VI.

Gas-chromatographic Fingerprint Investigations
In order to investigate potential organic leachable substances which may be released from Pekkton® ivory, a comparative analytical study was performed comparing the Pekkton® ivory extracts with extracts

prepared from PEKK based material. The materials were subjected to an aqueous and organic extraction followed by *GC/MS / ICP* analyses of the respective extracts. The study was performed in compliance with international GLP regulations and served the scope of a material characterization as requested by ISO 10993-18.
In summary, none of the investigated extracts of Pekkton® ivory, the tested PEKK based material exhibited any product-related peaks. This indicates that no potentially organic toxic leachable substances were released from the investigated material under the conditions of the test.

Cytotoxicity
The potential of cytotoxicity potential of Pekkton® ivory was investigated in compliance with international GLP regulations, using the biological in vitro cytotoxicity test with L929 mouse fibroblasts in accordance with EN ISO 10993-5.
Based upon the observed results and under the test-conditions chosen, the investigated material Pekkton® ivory can be evaluated to have no cytotoxic potential in terms of EN ISO 10993-5 when manufactured and applied in accordance with the instructions for use.

Cendres+Métaux SA evaluated the biological risks for irritation, delayed type-hypersensitivity, acute systemic toxicity, subchronic and chronic systemic toxicity, implantation, genotoxicity, carcinogenicity – reproductive and developmental toxicity – immunotoxicity for Pekkton® ivory. The clinical evaluation and testing demonstrated safety and effectiveness for its intended use. Pekkton® ivory holds the CE mark. No incidents or adverse events have been reported since its market launch.

Non-clinical test data was used to support the substantially equivalence claim. Clinical testing was not necessary. Non-clinical testing consisted of analysis of devices to identify worst-case test samples. The evaluation was based on FDA guidance "Guidance for Industry and FDA Staff, Dental Composite Resin Devices – Premarket Notification (510(k)) Submissions."
Chemical- and physical properties have been tested. Furthermore, bond strength to veneering composites, determination of the static fracture load and fatigue tests as well as simulated use tests have been conducted to evaluate the performance characteristics of Pekkton® ivory. The test methods were based on established standards and guidelines. Testing has shown that Pekkton® ivory is equivalent in performance characteristics to the predicate devices. The acceptance criteria were met.
The summary of chemical-, physical characteristics as well as application and functional testing indicate that the device is safe and effective for its intended use and performs as well or better than the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 21, 2013

Ms. Tanja Bongni
Regulatory Affairs Manager
Cendres + Métaux SA
Rue de Boujean 122
Biel/Bienne
Switzerland 2501

Re: K123638
Trade/Device Name: Pekkton® Ivory
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown and Bridge Resin
Regulatory Class: II
Product Code: EBG
Dated: October 30, 2012
Received: November 26, 2012

Dear Ms. Bongni:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123638

Device Name: Pekkton® ivory

Indications for Use: Pekkton® ivory is intended to be used for long-term, temporary dental crowns and bridges frameworks.

Prescription Use __X__ AND / OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner, DDS, MA
Mary S. Runner
2013.02.20
11:11:37 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K123638